UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

INTERNATIONAL INTIMATES, INC.,

Plaintiff,

vs.

MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE, LLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, PLC d/b/a MALLINCKRODT PHARMACEUTICALS; MALLINCKRODT, LLC; CVS HEALTH CORPORATION; RITE-AID OF MARYLAND, INC. RITE AID CORP; WALGREENS BOOTS ALLIANCE, INC.; WAL-MART INC.; JOHN DOES 1-100;

Defendants.

Civil Action No._____

OPIATE LITIGATION
MDL NO. 2804

COMPLAINT
(JURY TRIAL DEMANDED)

The Plaintiff, INTERNATIONAL INTIMATES, INC., a company providing health and welfare benefits to its employees and their families, (hereinafter referred to as Plaintiff), by and through its attorneys, files this Complaint against the Defendants as follows:

INTRODUCTION

1. The addiction epidemic of prescription opioid abuse in the United States has caused businesses, including Plaintiff, extraordinary economic damages. This opioid epidemic has financially damaged Plaintiff who seeks, in part, reimbursement of losses incurred as a result on the opioid epidemic including without limitation medical care, opioid-related illnesses, workers compensations and disability premium increases, employee downtime, employee retraining, employee counseling, and other costs.

2. Prescription opioids are deadlier than heroin, with related drug overdose deaths surpassing car accident deaths in the United States. The direct costs incurred by employers, including Plaintiff, are overwhelming.

3. This epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing the geographic area that Plaintiff serves to become flooded with prescription opioids.

4. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty by consciously ignoring known or knowable problems and data in their custody, control, and/or possession.

5. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have overflowed freely from and through the Defendants to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers.

6. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled

the opioid epidemic in Plaintiff's area, where the participants of Plaintiff and their families live and work. This is "opioid diversion." Acting against their common law and statutory duties, Defendants have caused a black market in opioid pills and other opioid drugs in which opioid diversion is rampant.

7. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the deaths and health ruination of hundreds of thousands of citizens. Substantial expenditures by Plaintiff in dealing with the problem have gone un-recouped and unreimbursed. All the Defendants share responsibility for perpetuating the epidemic.

8. Defendants have foreseeably caused damages to Plaintiff including the unreimbursed and/or un-recouped costs from the over-prescription of opioids.

9. Plaintiff brings this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendants opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed, dispensed, and/or over prescribed prescription opioid drugs in a manner that foreseeably injured and continues to injure Plaintiff.

10. Plaintiff has strived to hold and manage its resources and assets and to only play reasonable expenses. To succeed and flourish Plaintiff strives to prevent waste or to otherwise prohibit asset dilution. As a result of the misconduct of Defendants, Plaintiff has suffered unnecessary and wasteful diversion and diminution of its assets.

PARTIES

11. The Plaintiff is a company and an employer providing Health and welfare benefits

and other benefits to its employees and their families. At all relevant times, Plaintiff cost have increased directly or indirectly due to Defendant's Misconduct. Plaintiff have sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein, including but not limited to, incurring unreimbursed costs related to the over-prescription of opioids.

12. McKesson Corporation ("McKesson") has its principal place of business in San Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of participants of the Plaintiff.

13. Cardinal Health, Inc. ("Cardinal") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of participants of the Plaintiff.

14. AmerisourceBergen Corporation has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of the participants of the Plaintiff.

15. McKesson, Cardinal, and AmerisourceBergen are collectively referred to hereinafter as "Distributor Defendants."

16. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In

2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

17. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly- owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

18. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the United States, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in the United States, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Through interrelated operations like these, Teva Ltd. operates in the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva

USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "Cephalon.")

19. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as "Janssen."). Janssen manufactures, promotes, sells, and distributes drugs in the U.S., including the opioid Duragesic. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER.

20. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly- owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and

hydrocodone products in the U.S., by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

21. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. Allergan Finance, LLC is a wholly owned subsidiary of Allergan plc, which markets and sells Allergan plc's drugs in the United States. Allergan plc and Allergan Finance, LLC are collectively referred to herein as "Allergan." Allergan PLC, Allergan Finance, LLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis." Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on

December 30, 2008, and began marketing Kadian in 2009.

22. Mallinckrodt, PLC, an alien company doing business as Mallinckrodt Pharmaceuticals with its principal place of business in the United States in St. Louis, Missouri. Mallinckrodt, LLC is a Delaware limited liability company, also doing business as Mallinckrodt Pharmaceuticals, with its principal place of business in the United States in Hazelwood, Missouri. Mallinckrodt plc and Mallinckrodt LLC are collectively referred to herein as "Mallinckrodt." Malinckrodt is one of the largest manufacturers of the generic opioid oxycodone.

23. Cephalon, Janssen, Endo, Actavis, and Mallinckrodt are collectively referred to hereinafter as the "Pharmaceutical Defendants."

24. Defendant CVS Health Corporation ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States.

25. Defendant Rite-Aid of Maryland, Inc., d/b/a Rite Aid Mid Atlantic Customer Support Center, Inc. and Rite Aid Corp. ("Rite Aid"), are a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids throughout the United States.

26. Defendant Walgreen Boots Alliance, Inc., also known as Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed

prescription opioids throughout the United States.

27. Defendant Wal-Mart, Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Wal-Mart, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States.

28. Plaintiff presently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

JURISDICTION AND VENUE

29. Plaintiff brings this civil action in *In Re: National Prescription Opiate Litigation*, MDL 2804, and files directly in the Northern District of Ohio as permitted in Paragraph 6(a) of this Court's Case Management Order No. 1 dated April 11, 2018 (Doc. # 232).

30. Jurisdiction of this Court arises under the laws of the United States 28 U.S.C. § 1392 as the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of attorney's fees and costs.

31. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly, and severally, in the geographic area served by the Plaintiff that have caused all of the Plaintiff's damages and all of which form the bases of the causes of action in this

Complaint as against Defendants. Defendants have committed multiple torts and breaches within the geographic areas in which the Plaintiff serves, repeatedly and systematically.

32. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships with the Plaintiff, some or all of which form the basis of the causes of action in this Complaint as against Defendants.

33. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the geographic area served by the Plaintiff, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly with the Plaintiff by virtue of their distribution, dispensing, and sales of prescription opioids. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions committed against the Plaintiff, and the consequences and damages related to said wrongful actions, conduct, and omissions.

34. Order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order No. 1, dated April 11, 2018.

BACKGROUND FACTS

35. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

36. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium

poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

37. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

38. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in the geographic area served by the Plaintiff.

39. The Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients nationwide. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their

false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas served by the Plaintiff.

40. The Pharmaceutical Defendants' direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

41. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on detailing branded opioids to doctors.

42. The FDA has cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

43. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are,

in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

44. The Pharmaceutical Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

45. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

46. The Pharmaceutical Defendants deceptively marketed opioids nationwide through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

47. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

48. The Pharmaceutical Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

49. The Pharmaceutical Defendants marketed opioids through a small circle of doctors

who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

50. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

51. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

52. To convince the public and patients that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

53. The Pharmaceutical Defendants falsely claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed

a patient education brochure that falsely claimed opioid addiction is "less likely if you have never had an addiction problem"; (b) Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain*, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which falsely claimed that "[p]eople who take opioids as prescribed usually do not become addicted"; (d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "most people do not develop an addiction problem"; (e) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* which described as "myth" the claim that opioids are addictive; (f) a Janssen website falsely claimed that concerns about opioid addiction are "overestimated".

54. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

55. The FDA further exposed the falsity of the Pharmaceutical Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of

overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

56. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction".

57. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer- term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

58. The Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims are: (a) an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions.

59. Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in

stopping opioids after long-term use.

60. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.

61. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."

62. Pharmaceutical Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

63. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse.

64. These numerous, longstanding misrepresentations minimizing the risks of long- term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes

clear, there is "insufficient evidence to determine the long- term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long- term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

65. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative

treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

66. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid- tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain.

67. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

68. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with

chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

69. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

70. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

71. Mallinckrodt, one of the largest manufacturers of the generic opioid oxycodone, recently agreed to pay a $35 million penalty to resolve allegations by the U.S. Department of Justice that it failed to report suspicious drug orders. This is a record settlement of claims that a pharmaceutical drug manufacturer failed to properly notify the U.S. Drug Enforcement Administration of suspicious orders for drugs such as oxycodone. U.S. Attorney General Jeff

Sessions said "Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street." According to the Justice Department, from 2008 to 2011, Mallinckrodt supplied distributors increasingly excessive amounts of oxycodone pills without notifying the DEA of the suspicious orders. Those distributors in turn supplied the drugs to various U.S. pharmacies and pain clinics, the Justice Department said. Mallinckrodt, however, continues to deny culpability to the public and the medical community. Michael-Bryant Hicks, Mallinckrodt's general counsel, said the company chose to settle "to eliminate the uncertainty, distraction and expense of litigation and to allow the company to focus on meeting the important needs of its patients and customers."

72. As a part of their deceptive marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Tennessee, Mississippi, Arkansas and Kentucky, and the geographic area served by the Plaintiff. For example, these Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

73. The Pharmaceutical Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. These Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and

recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

74. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo has recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

75. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the

accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

76. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Janssen, ran similar websites that masked their own direct role.

77. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff.

78. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

79. The Pharmaceutical Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and

patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

80. The Pharmaceutical Defendants' deceptive marketing scheme caused and continues to cause doctors to prescribe opioids for chronic pain conditions. Absent these Defendants' deceptive marketing scheme, these doctors would not have prescribed the quantity of opioids. These Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

81. The Pharmaceutical Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

82. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. In August 2016, the U.S. Surgeon General published an open letter to besent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were

even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

83. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

84. Contrary to the Pharmaceutical Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

85. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

86. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually

large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

87. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the transaction. These signs or "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication for purposes to treat a legitimate medical condition. In addition to diversion via prescription, opioids are also diverted from retail outlets when stolen by employees or others.

88. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

89. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

90. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose and death.

91. Within the last 20 years, the abuse of prescription narcotic pain relievers has

emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids are at epidemic proportions, quadrupling since 1999, concomitant with sales of these prescriptions.

92. In 2011 overdose deaths from prescription opioids reached 16,917 people. In 2014 18,893 people died from a prescription opioid related overdose. In 2015, the number of deaths increased to 22,598, even despite increased public health announcements.

93. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people died from heroin overdose-up more than 20% from approximately 10,574 overdose deaths in 2014.

94. The Plaintiff has taken proactive measures to fight against prescription opioid abuse.

95. The Plaintiff, uniquely and significantly, has been damaged by the effects of the Distributor Defendants' opioid diversion.

96. The CDC reports that for every opioid-related death, there are on average 10 hospital admissions for abuse, 26 emergency department visits for misuse, 108 people who are dependent on opioids, and 733 non-medical users.

97. Defendants' opioid diversion has caused and will continue to cause Plaintiff's damages, including greater expenditures by Plaintiff.

98. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

99. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq. and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

100. By violating the CSA, the Distributor Defendants are also liable under the common law as herein alleged.

101. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

102. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit

marketplace, and there is enormous potential for harm to the public.

103. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report susp1c1ous orders, conduct due diligence, and terminate orders if there are indications of diversion.

104. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("'ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on the distribution of controlled substances, acquisition transactions, and distribution transactions, which are summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

105. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for

each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

106. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

107. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR §1301.71.

108. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, yet have committed repeated violations of the laws and regulations of the United States as cited above consequently making them liable under common law.

109. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and

report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.

110. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

111. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

112. The September 27, 2006 letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion,

the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

113. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

114. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

115. These industry guidelines stated: "At the center of a sophisticated supply chain,

distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

116. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

117. For example, a Cardinal executive claimed that Cardinal uses “advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity." (emphasis added).

118. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

119. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

120. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

121. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the Controlled

Substances Act.

122. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million-dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

123. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

124. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to

Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

125. Relying upon state laws and regulation, various State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

126. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

127. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff.

128. The Distributor Defendants have supplied massive quantities of prescription opioids in and around the geographic areas served by Plaintiff with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non- medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

129. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into the geographic areas served by Plaintiff was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those

communities).

130. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the geographic area served by Plaintiff; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

131. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing participants of Plaintiff and in the geographic area served by its funds to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

132. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the participants of Plaintiff and in the geographic area served by its fund, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

133. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the member market of Plaintiff and in the geographic area served by its fund with highly-

addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

134. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including illnesses, overdoses, and death. It is also reasonably foreseeable that the costs of these injuries will be shouldered by Plaintiff.

135. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid costs of Plaintiff, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of illnesses, demand, illegal transactions, economic ruin, and human tragedy.

136. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to participants of Plaintiff and in the geographic area served by it were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, and Plaintiff.

137. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become participants of Plaintiff, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency- that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

138. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Plaintiff would have avoided significant damages.

139. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting Plaintiff. Their participation and cooperation in a common enterprise

has foreseeably caused damages to Plaintiff. The Distributor Defendants knew full well that Plaintiff would be unjustly forced to bear the costs of these injuries and damages.

140. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff. Their conduct poses a continuing economic threat to Plaintiff.

141. The Pharmaceutical Defendants, including specifically Mallinckrodt, have engaged in similar wrongful conduct as alleged hereinabove as the Distributor Defendants.

COUNT I: NUISANCE

142. The Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

143. The nuisance is the over-saturation of opioids to Plaintiff geographic area served by Plaintiff for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

144. All Defendants substantially participated in nuisance-causing activities.

145. Defendants' nuisance-causing activities include the distribution of prescription opioids to the Plaintiff's employees and their families, as well as to unintended users, including children, and people at risk of overdose or suicide, and criminals, which have caused Plaintiff damages.

146. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

147. Defendants' activities unreasonably interfere with the economic rights of Plaintiff.

148. The Defendants' interference with these rights of Plaintiff is unreasonable because it:

a. Has harmed and will continue to harm the health services of and public peace of Plaintiff;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiff services;

c. Is proscribed by statutes and regulation;

d. Is of a continuing nature and it has produced long-lasting effects; and

e. Defendants have reason to know their conduct has a significant, adverse effect upon Plaintiff.

149. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within participants and their families and entire communities.

150. The Plaintiff resources of funds have been unreasonably consumed as a result of addressing the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

151. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from points of sale and diversion.

152. As a direct and proximate result of the nuisance, Plaintiff have sustained economic harm caused by Defendants' nuisance-causing activity.

153. Plaintiff has also suffered unique harms different from individual opioid users and governmental entities at large, namely, that Plaintiff have been harmed in its proprietary and financial interests.

154. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE

155. The Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

156. Defendants owe a non-delegable duty to Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

157. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

158. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, and safety of the employees of Plaintiff.

159. Defendants' behavior caused a substantial injury and damage to Plaintiff.

160. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

a. Consciously supplying the market in the geographic area served by Plaintiff with highly-addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;

b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential participant;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Failing to properly train or investigate their employees;

e. Failing to properly review and analyze prescription orders and data for red flags;

f. Failing to report suspicious orders or refuse to fill them;

g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;

h. Failing to police the integrity of their supply chains; and

i. Creating misleading information with the intention of having prescribing physicians rely upon it.

161. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

162. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every participant, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

163. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

164. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

165. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt employees, doctors, and/or criminals who buy and sell or otherwise acquire opioids for non-medical purposes, all of which has resulted in damages to Plaintiff.

166. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-

vis Plaintiff and its participant communities. Defendants owe a special duty to Plaintiff. That duty cannot be delegated to another party.

167. Plaintiff is without fault, and the injuries to Plaintiff would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

168. The aforementioned conduct of Defendants proximately caused damage to Plaintiff.

COUNT III: UNJUST ENRICHMENT

169. Plaintiff reasserts the allegations in the foregoing paragraphs as if set forth fully herein.

170. Plaintiff has expended substantial amounts of money as a result of addiction, illnesses, and medical conditions of its participants and their families caused by Defendants' conduct.

171. The expenditures by Plaintiff's employees and their families who use opioids have added to Defendants' wealth. The expenditures by Plaintiff have helped sustain Defendants' businesses.

172. Plaintiff have conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities - the costs of the harm caused by Defendants' negligent distribution and sales practices.

173. Defendants are aware of this obvious benefit, and that retention of this benefit is unjust.

174. Defendants made substantial profits while fueling the prescription drug epidemic.

175. Defendants continue to receive considerable profits.

176. Defendants have been unjustly enriched by their negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

177. It would be inequitable to allow Defendants to retain the benefit or financial advantage of their wrongdoing.

178. Plaintiff demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

COUNT IV: COMMON LAW FRAUD
(AS TO PHARMACEUTICAL DEFENDANTS ONLY)

179. Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

180. Pharmaceutical Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

181. Defendants made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term functioning long- term and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety

and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including rates of abuse and addiction and the lack of validation for long-term efficacy; (k) misleading statements in education materials for nationwide hospital doctors and staff under guise of educating them on new pain standards; (l) in-person detailing; and (m) withholding from law enforcement the names of prescribers Defendants believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs.

182. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain,

including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

183. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain and; (k) in-person detailing.

184. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements minimizing the risk of addiction of opioids, promoting the concept of pseudo-addiction, advocating the use of opioids for chronic non-cancer pain, funding misleading CMEs, KOL doctors, and pain organizations, minimizing the addictiveness of Cephalon's potent rapid-onset opioids, and promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

185. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to Tennessee, Mississippi, Arkansas and Kentucky prescribers through in-person detailing; (b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; (c) advertising that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

186. These false representations and concealments were reasonably calculated to deceive prescribing physicians in the geographic areas served by Plaintiff, were made with the intent to deceive, and did in fact deceive physicians who prescribed opioids for chronic pain.

187. But for these false representations and concealments of material fact, Plaintiff would not have incurred substantial costs and economic loss.

188. As a direct and proximate cause of the Pharmaceutical Defendants' fraudulent conduct, Plaintiff have suffered damages.

COUNT V: CIVIL CONSPIRACY

189. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out herein.

190. The Pharmaceutical Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their common law duties and violating the CSA. The Distributor Defendants continuously flooded prescription opioids in the pertinent geographic areas despite having actual or constructive knowledge that said opioid pills were being overprescribed, illegally diverted, and/or otherwise abused, all in violation of the CSA.

191. No Defendant in this opioid network would have succeeded in profiting so

significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

192. The Pharmaceutical Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Pharmaceutical Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Pharmaceutical Defendants ignored the warning signs of opioid diversion.

193. As a result of the concerted actions between and among the Defendants, Plaintiff have suffered damages.

194. Plaintiff demand judgment against each Defendant for compensatory damages.

COUNT VI: RACKETEERING INFLUENCED AND CORRUPT ORGANIZATIONS ACT U.S.C. §§ 1961, ET SEQ.

195. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

196. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3) because they are capable of holding, and do hold, "a legal or beneficial interest in property."

197. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity...." 18 U.S.C. § 1962(c). Each Defendant conducted and participated in the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

198. Article 460.20 of the New York Penal Law states: "A person is guilty of enterprise corruption when, having knowledge of the existence of a criminal enterprise and the nature of its

activities, and being employed by or associated with such enterprise, he:

a. intentionally conducts or participates in the affairs of an enterprise by participating in a pattern of criminal activity; or

b. intentionally acquires or maintains any interest in or control of an enterprise by participating in a pattern of criminal activity; or

c. participates in a pattern of criminal activity and knowingly invests any proceeds derived from that conduct, or any proceeds derived from the investment or use of those proceeds, in an enterprise."

A. The Enterprise and Conduct of Defendants

199. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" Turkette, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

200. Article 460.10 of New York Penal Law defines an enterprise as a "group of persons sharing a common purpose of engaging in criminal conduct, associated in an ascertainable structure distinct from a pattern of criminal activity, and with a continuity of existence, structure and criminal purpose beyond the scope of individual criminal incidents."

201. Defendants formed an association-in-fact Enterprise and participated in the affairs

of the Enterprise to increase the market for opioids through a pattern of racketeering activity. The Enterprise consists of (1) the Manufacturer Defendants, including their employees and agents, (2) Front Groups, including their employees and agents, (3) the KOLs, and (4) the Distributor Defendants. The Enterprise's purpose was to fabricate a new market for opioids in chronic pain treatment and sell as many opioid products as possible through deception and willfully ignoring requirements to curtail the illegal drug market that the Enterprise's conduct created.

202. To accomplish this purpose, the Enterprise systematically misrepresented to the general public, doctors, and insurers the risks of using opioids for chronic pain, and flouted requirements to investigate and prevent the ensuing waive of suspicious orders. The Manufacturer Defendants, Front Groups, KOLs, and Distributor Defendants all conducted and participated in the affairs of the Enterprise by distributing false statements through the wires or mail or by violating the Controlled Substances Act. This campaign of illegality and misinformation translated into profits for all Defendants, and funding and payments to Front Groups and KOLs.

203. The participants in the Enterprise are systematically linked through contractual relationships, financial ties, and continued coordination of activities, spearheaded by the Manufacturer Defendants. There is regular communication between the Manufacturer Defendants, Distributor Defendants, Front Groups, and KOLs in which information is shared. This communication typically occurs, and continues to occur, through the use of the wires and mail in which the participants share information regarding overcoming objections to the use of opioids for chronic pain.

204. The Distributor Defendants were willing participants in, and beneficiaries of, the Enterprise's campaign of deception. The Distributor Defendants profited from the Enterprise's newly-expanded opioid market and furthered the Enterprise's goal of profiting from that market

by flouting legal requirements to report suspicious ordering. By the Distributor Defendants' violating the CSA's requirements to prevent diversion, all Defendants were able to profit from both the legal and illegal drug markets created by the Enterprise's success in establishing the long-term opioid treatment market and the ensuing addiction crisis. The Distributor Defendants were aware of the campaign of deception engineered by the Manufacturing Defendants, KOLs, and Front Groups, but sought only to profit from the Enterprise's deception.

205. The Distributor Defendants are intimately connected with the Manufacturer Defendants through their industry organization, the HDA. According to the HDA's website, the HDA's executive committee includes an executive from each Distributor Defendant. Each Manufacturer Defendant is also a member of HDA.

206. HDA specifically advertises its benefits as a forum for meeting with distributors. The Distributor Defendants used membership in the HDA as an opportunity to create working relationships with Manufacturer Defendants. HDA, in turn, is a member of PCF. Each Manufacturer Defendant, or a related company, is a member of PCF.

207. Together, Defendants lobbied state governments and Congress to undermine enforcement and legal limitations that would otherwise have interfered with increased opioid sales. Between 2006 and 2015, the PCF spent more than $740 million lobbying to influence local, state and federal governments, including on opioid-related measures. The HDA and PCF lobbied for passage of the Ensuring Patient Access and Effective Drug Enforcement Act, which hobbled the DEA's ability to suspend or revoke registrations, permitting Distributor Defendants to further the Enterprise's goal of increasing opioid sales without regard to legal requirements or the effects on Massachusetts residents. Defendants' coordination through the HDA, PCF, and lobbying activities—while not racketeering activity—evidence Defendants' knowledge of the structure of

the Enterprise and purposeful participation in it.

208. At all relevant times, Front Groups were knowing and willing participants in the Enterprise's conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme. But for the Enterprise's unlawful scheme, Front Groups would have had the incentive to disclose the deceit by the Manufacturer Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Enterprise's scheme and reaped substantial benefits.

209. At all relevant times, KOLs were knowing and willing participants in the Enterprise's conduct, and reaped profits from that conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Manufacturer Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of Plaintiff and Class Members. But for the Enterprise's unlawful scheme, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Enterprise's scheme, and reaped substantial benefits.

210. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

211. The Front Groups and KOLs participated in the conduct of the Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of wire and mail fraud, knowingly made material misstatements to physicians, consumers, and the general public in furtherance of the scheme, including that:

a. it was rare, or there was a low risk that the Manufacturer Defendants' opioids could lead to addiction;

b. the signs of addiction were actually signs of undertreated pain, known as "pseudoaddiction" that should be treated by more opioids.

c. doctors and patients could increase opioid dosages indefinitely without risk; and

d. long term opioid use improved patients' function and quality of life.

212. Without the misrepresentations of the Front Groups and KOLs, who were perceived as neutral and scientific, the Defendants alone could not have accomplished the purposes of the Enterprise.

213. During the time period described in this Complaint, the Manufacturer Defendants exerted control over the Enterprise and participated in the operation and management of the affairs of the Enterprise, directly or indirectly, in the following ways:

a. The Manufacturer Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. The Manufacturer Defendants selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute the Manufacturer Defendants' messages about the use of opioids for chronic pain;

c. The Manufacturer Defendants provided substantial opportunities for KOLs to participate in research studies on topics the Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. The Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. The Manufacturer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. The Manufacturer Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. The Manufacturer Defendants developed and disseminated pro-opioid treatment guidelines;

h. The Manufacturer Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturer Defendants, such as veterans and the elderly, and then funded that distribution;

i. The Manufacturer Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large;

j. The Manufacturer Defendants intended that Front Groups and KOLs would

distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain; and

k. The Manufacturer Defendants, Front Groups, and KOLs minimized the fact that opioids were being diverted due to the Distributor Defendants' misconduct.

214. During the time period described in this Complaint, the Distributor Defendants conducted and participated in the affairs of the Enterprise in the following ways:

a. The Defendants violated the Controlled Substances Act and caused massive diversion of opioids by failing to investigate suspicious orders;

b. The Distributor Defendants violated the Controlled Substances Act by failing to maintain adequate controls against diversion of prescription opioids;

c. The Distributor Defendants refused to identify, investigate or report suspicious orders of prescription opioids being diverted into the illicit drug market; and

d. The Distributor Defendants made false and misleading statements attempting to minimize their responsibility for preventing diversion and representing that they complied with the law.

215. The scheme had a hierarchical decision-making structure that was headed by the Manufacturer Defendants. The Manufacturer Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with the Manufacturer Defendants' messaging nationwide and throughout the Commonwealth of Massachusetts. Front Groups were dependent on the Manufacturer Defendants for their financial support, and KOLs were professional dependent on the Manufacturer Defendants for the development and promotion of their careers. The Distributor Defendants worked hand-in-hand with the Manufacturer Defendants to limit government

enforcement and increase sales of opioids through industry groups like the HDA and the PCF.

216. For the foregoing reasons, all Defendants, Front Groups, and KOLs were each willing participants in the Enterprise, had a common purpose and interest in furthering opioid prescribing and increasing sales of opioids without regard to diversion, and functioned within a structure designed to effectuate the common purpose.

217. The scheme devised and implemented by all Defendants, as well as other members of the Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment from insurers for Defendants' opioids. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

218. The Enterprise was intended to and did affect interstate commerce, in that the statements made by the members of the Enterprise were passed through the wires or mail over state lines, and that the Enterprise increased sales of opioids through the channels of interstate commerce.

219. The impacts of the Enterprise continue to be felt, as opioids continue to be prescribed and used for chronic pain. Plaintiff continues to pay for the fallout from the Enterprise as insurers pass on the costs of opioid addiction and treatment.

B. Pattern of Racketeering Activity

220. The Manufacturer Defendants, Front Groups, and KOLs conducted and participated in the conduct of the Opioid Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as

defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

221. The Manufacturer Defendants, Front Groups, and KOLs all made misrepresentations detailed above in service of a scheme to deceive which was intended to, and did, deceive consumers, doctors and insurers about the safety and efficacy of opioid use. All were passed through the wires and/or mail, and constituted predicate acts within the meaning of RICO, including:

a. The dissemination via wires and mail of APF's Treatment Options beginning in 2007 and continuing afterward, which misrepresented the risks of addiction, promulgated the false concept of pseudoaddiction, falsely represented that doctors and patients could increase opioid dosages without risk, and falsely represented that long-term opioid use could improve patients' quality of life;

b. The dissemination via wires and mail of APF's Policymaker's Guide beginning in 2011 and continuing afterward, which misrepresented the risks of addiction and falsely represented that doctors and patients could increase opioid dosages indefinitely without risk;

c. The dissemination via wire of Endo's pamphlet, edited by Russel Portenoy, Understanding Your Pain, available on Endo's website throughout the time period described in this Complaint, which falsely represented that doctors and patients could increase opioid dosages without risk;

d. The dissemination via wires and mail of Responsible Opioid Prescribing, beginning in 2007 and afterward, which promulgated the false concept of pseudoaddiction and falsely represented that long-term opioid use could improve patients' quality of life;

and

e. The dissemination via wires and mail of the misrepresentations and false statements detailed in this complaint herein.

222. The Distributor Defendants engaged in the violations of the law detailed above to enable the Enterprise to profit from its deceptive creation of the expanded market for opioids. Distributor Defendants' activities were coordinated and planned with the Manufacturer Defendants, as evidenced by coordinated lobbying efforts to weaken DEA enforcement. Distributor Defendants, through their relationships with the Manufacturer Defendants, were aware of the Enterprise's deceptive activity and sought only to enable the Enterprise to profit from it. To do so, Distributor Defendants engaged in the following predicate acts:

a. Cardinal's violations of the CSA and federal law concerning the distribution of controlled substances in 2008, 2012, and 2016, which resulted in fines, penalties or settlements with the DEA;

b. McKesson's violations of the CSA and federal law concerning the distribution of controlled substances in 2008 and 2017 which resulted in fines, penalties or settlements with the DEA; and

c. AmerisourceBergen's violations of the CSA and federal law concerning the distribution of controlled substances in 2007 and 2012 that resulted in penalties and an investigation by the Department of Justice.

223. Many of the precise dates of the Defendants' coordination have been hidden and cannot be alleged without access to the Defendants' records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy.

224. The Manufacturer Defendants', the Front Groups', and KOLs' deceptive activities

were coordinated and planned in advance, as evidenced by the Front Groups' and KOLs' misleading statements described above that were supported, funded, or compensated by the Manufacturer Defendants. Many of the precise dates of the Manufacturer Defendants', Front Groups', and KOLs' agreement to violate RICO, however, have been hidden and cannot be alleged without access to the Manufacturer Defendants', the Front Groups', and the KOLs' books and records. Indeed, for the deception to be successful, the coordination between the Manufacturer Defendants and the seemingly-independent Front Groups and KOLs had to remain secret.

225. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including doctors, insurers, and consumers in Massachusetts. The Manufacturer Defendants, the Front Groups, and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on Plaintiff and Class Members. The Distributor Defendants knowingly and intentionally assisted the Enterprise in cashing in on the market that the Enterprise's deceptive conduct created.

226. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, subsequently failing to disclose such practices, and profiting off of the legal and illegal market that deception created, the Manufacturer Defendants, the Distributor Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

C. Damages

227. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused Plaintiff to be injured in its business or property in the form of increases

costs.

228. But for Defendants', the Front Groups', and the KOLs' racketeering activities, Plaintiff and Class Members would not have paid the increases in insurance premiums associated with the opioid epidemic. It was foreseeable that Defendants' racketeering activities would result in insurers' losses in the form of (1) overpayment for ineffective drugs, and (2) massive healthcare costs associated with opioid addiction, and that those costs would be passed on to Plaintiff.

229. Plaintiff seek all legal and equitable relief permitted by RICO, including equitable relief, actual damages, treble damages, and attorneys' fees.

COUNT VII: CONSPIRACY TO VIOLATE THE RACKETEERING INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §§1961, ET SEQ.

230. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

231. Plaintiff brings this claim on its own behalf against all Defendants. At all relevant times, the RICO Defendants were associated with the opioid "enterprise" and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Enterprise through a pattern of racketeering activity.

232. Defendants conspired, as alleged more fully above, by conducting the affairs of the Opioid Enterprise through a pattern of racketeering activity, as incorporated herein by reference.

233. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

234. Plaintiff's injuries, were proximately caused by the Defendants' racketeering

activities. But for the Defendants' conduct, Plaintiff would not have made expenditures required as a result of the plague of drug-addicted residents.

235. Plaintiff's injuries were directly caused by the Defendants' racketeering activities.

236. Plaintiff seeks all legal and equitable relief permitted by RICO, including equitable relief, actual damages, treble damages, and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays that the Court grant the following relief:

a. Injunctive Relief;

b. Civil Penalties;

c. Compensatory damages;

d. Restitution;

e. Punitive Damages;

f. Attorneys' fees and costs; and

g. All such other relief this Court deems just and fair;

h. Plaintiff seeks a trial by jury for all counts so triable.

Plaintiff demands trial by jury on all counts so triable.

Dated, this the 23rd day of October, 2019.

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